

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

Prasco, LLC,

Plaintiff,

v.

Case No. 1:06cv313

Medicis Pharmaceutical Corp., *et al.*,

Judge Michael R. Barrett

Defendants.

ORDER

This matter is before the Court Plaintiff Prasco's Motion to Alter or Amend. (Doc. 34) Defendants Medicis Pharmaceutical Corporation ("Medicis") and Imaginative Research Associates, Inc.'s ("Imaginative") have filed a Response in Opposition (Doc. 35), and Prasco has filed a Reply (Doc. 36). This matter is now ripe for review.

I. FACTUAL AND PROCEDURAL BACKGROUND

Defendant Medicis manufactures and markets the product TRIAZ. This product has four patents associated with it: U.S. Patent Nos. 5,254,334 ('334); 5,409,706 ('706); 5,632,996 ('996); and 5,648,389 ('389). Medicis is the assignee for the '389 patent and is the licensee for the '334, '706, and '996 patents. Defendant Imaginative is the assignee for the '334, '706, and '996 patents, and licenses these patents to Medicis.¹ TRIAZ is an acne cleanser containing benzoyl peroxide in the concentrations 3%, 6%, and 9%. Medicis commercially markets TRIAZ as being covered by the patents-in-suit, and labels the

¹The parties dispute whether Medicis, as licensee, would have the right to enforce the three Imaginative patents. The Court once again finds it unnecessary to reach this issue given the disposition of this motion.

packaging and labeling with these patent numbers.

On May 5, 2006, Prasco filed its Complaint for declaratory judgment, seeking a declaration that its product OSCION has not infringed, does not infringe, and will not infringe any valid and enforceable claim of the patents-in-suit. OSCION is a generic acne cleanser also containing benzoyl peroxide in the concentrations 3%, 6%, and 9%. OSCION is designed as a fully substitutable generic alternative to TRIAZ and intended to compete directly with it. Prior to the filing of the declaratory action, Prasco had not begun to market OSCION, and Defendants had no knowledge of Prasco's product. (Doc. 15, Ex. 1, Brandon Hokenstad Decl. ¶ 3; Doc. 15, Ex. 2, Mohan Vishnupad Decl. ¶¶ 4-5)

Defendants moved to dismiss Prasco's Complaint, arguing that this Court lacked subject matter jurisdiction because Prasco had not sufficiently alleged a case or controversy. Prasco responded by filing an Amended Complaint, which states that on June 14, 2006, Prasco commercially launched OSCION. (Doc. 17 ¶ 29). Prasco alleged that on July 28, 2006, it provided Medicis and Imaginative with a sample of OSCION, its related labeling, and an ingredient list. (Id. ¶ 31) Prasco also alleged that on July 28, 2006 it requested from Medicis and Imaginative a covenant not to sue relating to the '334, '706, '996, and '389 patents; but Medicis and Imaginative have refused this request. (Id. ¶¶ 35-38) Defendants moved to dismiss the Amended Complaint.

In ruling upon Defendants' Motions to Dismiss, this Court found that based on the facts alleged in the Amended Complaint, Prasco had not alleged conduct sufficient to objectively establish a "reasonable apprehension of suit" by Defendants, and therefore the Court did not have subject matter jurisdiction over Prasco's claims. In a footnote, the Court also noted that even if the reasonable apprehension of suit test is no longer good law,

there is no actual case or controversy present based upon the facts in the record.

II. ANALYSIS

A. Motion to Alter or Amend

Prasco brings its motion pursuant to Federal Rule of Civil Procedure 59(e). Under this Rule, there are three grounds for amending a judgment: (1) to accommodate an intervening change in controlling law; (2) to account for new evidence not available at trial; and (3) to correct a clear error of law or to prevent manifest injustice. *GenCorp., Inc. v. Am. Int'l Underwriters*, 178 F.3d 804, 834 (6th Cir. 1999); *Berridge v. Heiser*, 993 F.Supp. 1136, 1146-47 (S.D. Ohio 1997). However, "[a] motion under Rule 59(e) is not an opportunity to re-argue a case." *Sault Ste. Marie Tribe of Chippewa Indians v. Engler*, 146 F.3d 367, 374 (6th Cir. 1998).

Prasco's motion is based upon an intervening change in controlling law. Prasco argues that a Federal Circuit decision issued three days after this Court's Order indicates that the United States Supreme Court overruled the "reasonable apprehension of suit test" in *MedImmune, Inc. v. Genetech, Inc., et al*, 127 S.Ct. 764 (January 9, 2007). See *Teva Pharms. USA, Inc. v. Novartis Pharms. Corp.*, 482 F.3d 1330, 1339 (Fed. Cir. Mar. 30, 2007).²

B. The Reasonable Apprehension of Suit Test

In *MedImmune*, the Supreme Court stated that the Federal Circuit's "reasonable apprehension of suit" test contradicts earlier Supreme Court precedent. 127 S.Ct. at 774, n.11. This Court found that while the Court's decision may call into doubt the use of the

²As the Federal Circuit acknowledges, this Court was bound by Federal Circuit precedent to apply the reasonable apprehension of suit test. See *Teva*, 482 F.3d at 1339.

"reasonable apprehension of suit" test, it did not overrule the line of cases that rely upon the "reasonable apprehension of suit" test. *Accord BridgeLux, Inc. v. Cree, Inc.*, No. 06-6495, 2007 WL 521237, at *2 (N.D.Cal. Feb. 15, 2007) (slip op.); *WS Packaging Group, Inc. v. Global Commerce Group, LLC*, No. 06-674, 2007 WL 205559, at *3 (E.D. Wisc. Jan. 24, 2007) (slip op.). The Federal Circuit has since determined that the Supreme Court's analysis in *MedImmune* is the proper approach. *See Teva Pharmaceuticals USA, Inc. v. Novartis Pharmaceuticals Corp.*, 482 F.3d 1330, 1338 (Fed. Cir. March 30, 2007). Under this approach, a declaratory judgment plaintiff must show that under "all the circumstances" an actual or imminent injury caused by the defendant that can be redressed by judicial relief and that is of "sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *Id.* at 1338, *quoting MedImmune*, 127 S.Ct. at 771. An "actual controversy" requires only that a dispute be " 'definite and concrete, touching the legal relations of parties having adverse legal interests'; and that it be 'real and substantial' and 'admi[t] of specific relief through a decree of a conclusive character, as distinguished from an opinion advising what the law would be upon a hypothetical set of facts.' " *Id.* at 1339, *quoting MedImmune*, 127 S.Ct. at 771.

In *Teva*, the court determined that when taken as a whole, the five grounds alleged by the plaintiff were sufficient to establish a justiciable controversy. *Id.* at 1341. First, the defendant listed its five related patents in the Food and Drug Administration's Orange Book, which the court recognized as a representation by the defendant that a claim of patent infringement could reasonably be asserted against a person not licensed by the owner. *Id.* Second, the plaintiff submitted its Abbreviated New Drug Application ("ANDA") certifying that it did not infringe the defendant's Orange Book patents or that the patents

were invalid. *Id.* at 1342. The court noted that the very act of submitting an ANDA is an act of infringement. *Id.* Third, the court noted that the defendant had filed an infringement lawsuit on only one of its five patents listed in the Orange book. *Id.* at 1343. The court found that the defendant's actions insulated its other four patents from a validity challenge, and frustrated the central purpose of the Hatch-Waxman Act of bringing cheaper generic drugs to market as quickly as possible. *Id.* at 1343-44. Fourth, the court found that the defendant's pending infringement litigation "involving the same technology and the same parties is relevant to determining whether a justiciable declaratory judgment controversy exists on other related patents." *Id.* at 1344-45, citing *Vanguard Research, Inc. v. PEAT, Inc.*, 304 F.3d 1249, 1255 (Fed. Cir. 2002) (finding a justiciable declaratory judgment controversy where the defendant had sued the declaratory judgment plaintiff for misappropriation of trade secrets thereby demonstrating "a willingness to protect [its] technology."); *Goodyear Tire & Rubber Co. v. Releasomers, Inc.*, 824 F.2d 953, 955 (Fed.Cir. 1987) (finding a justiciable declaratory judgment controversy in a patent non-infringement and invalidity action where the defendant had sued the declaratory judgment plaintiff in state court for misappropriation of trade secrets involving the same technology, thereby engaging in "a course of conduct that shows a willingness to protect

that technology.”).³ Finally, the court noted that the defendant’s election to sue on only one of its five related patents left open the possibility of future litigation. *Id.* at 1345. The court explained that even if the plaintiff is successful in defending the pending infringement suit, it remains subject to four additional infringement actions by the defendant, which could result in protracted litigation. *Id.*

Prasco attempts to bring the facts alleged in the Amended Complaint within the holding of *Teva*. Prasco argues that the following circumstances establish that there is an actual controversy between the parties: (1) Defendants have marked the patents-in-suit on Medicis’ product; (2) Medicis has previously sued Prasco for infringement of a patent for a similar product; and (3) Defendants are unwilling to provide Prasco with a covenant no-to-sue.

The Court finds that these facts, unlike the circumstances in *Teva*, do not establish an actual controversy. Even if the Court were to find that the marking of products with the patents-in-suit is analogous to a listing of patents in the Orange Book, the court in *Teva* was clear that this conduct alone is not sufficient to establish an Article III controversy. 482 F.3d at 1341-42. In *Teva*, the court found dispositive that the plaintiff was an ANDA filer, the defendant had listed patents in the Orange Book, the plaintiff had filed its ANDA

³As the court explained:

A justiciable declaratory judgment controversy arises for an ANDA filer when a patentee lists patents in the Orange Book, the ANDA applicant files its ANDA certifying the listed patents under paragraph IV, and the patentee brings an action against the submitted ANDA on one or more of the patents. The combination of these three circumstances is dispositive in establishing an actual declaratory judgment controversy as to all the paragraph IV certified patents, whether the patentee has sued on all or only some of the paragraph IV certified patents.

482 F.3d at 1344.

certifying the listed patents under paragraph IV, and the defendant brought an action against the submitted ANDA on one or more of the patents. *Id.* at 1344. None of these circumstances exist in the present case. The only litigation which Prasco can point to is the Arizona infringement suit Medicis filed against Prasco and another generic company.⁴ That litigation involved a different product—Prasco's PRASCION product—and a different patent owned by Medicis. Prasco has not alleged that the Arizona litigation involved the same technology as the patents in this action. Without this connection, the Court cannot conclude that the Arizona litigation demonstrates any possibility of future litigation.

Finally, the Court finds that Medicis' refusal grant a covenant not to sue holds little weight under the circumstances. While Defendants have not conceded non-infringement, Prasco cannot point to any statements by Defendants indicating that Defendants take a position that Prasco's OSCION product infringes the patents-in-suit. In contrast, in *Sandisk Corp. v. STMicroelectronics, Inc.*, 480 F.3d 1372, 1382 (Fed. Cir. 2007), the declaratory judgment plaintiff alleged that the defendant sought a royalty under its patents based on specific, identifiable activity by the plaintiff. The parties had engaged in licensing negotiations, during which the defendant presented the plaintiff with a thorough infringement analysis prepared by seasoned litigation experts. *Id.* The court found that despite the defendant's promise not to sue, its acts did not render moot the actual controversy created by its acts. *Id.* at 1383. The court concluded that under the facts alleged, the plaintiff had established an Article III case or controversy that gives rise to

⁴On October 27, 2005 Medicis filed a complaint against Prasco and another generic company in federal court in Arizona seeking a declaration that Prasco's product PRASCION infringed another of Medicis' patents. (Doc. 17, ¶ 40)

declaratory judgment jurisdiction. *Id.* at 1382. Here, Prasco has not alleged that Defendants have initiated discussions regarding licensing or made any statements regarding infringement. Without such facts, the Court cannot find that under all the circumstances, Prasco has shown that there is a substantial controversy of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

Therefore, the Court **DENIES** Plaintiff Prasco's Motion to Alter or Amend (Doc. 34); and this case shall remain **CLOSED**.

IT IS SO ORDERED.

/s/ Michael R. Barrett
Michael R. Barrett, Judge
United States District Court